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S. 2278

To improve the prevention, detection, and treatment of community and healthcare-associated infections (CHAI), with a focus on antibiotic-resistant bacteria.

IN THE SENATE OF THE UNITED STATES

OCTOBER 31, 2007

Mr. DURBIN (for himself, Mr. OBAMA, and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve the prevention, detection, and treatment of community and healthcare-associated infections (CHAI), with a focus on antibiotic-resistant bacteria.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Community and
5 Healthcare-Associated Infections Reduction Act of 2007”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Effective antibiotics have transformed the
9 practice of medicine and saved millions of lives, but

1 the emergence and spread of antibiotic-resistant bac-
2 terial pathogens poses a significant threat to patient
3 and public health.

4 (2) Although many antibiotic-resistant infec-
5 tions occur most frequently among individuals in
6 hospitals and other healthcare facilities, they also af-
7 fect otherwise healthy individuals in the community.

8 (3) According to the Centers for Disease Con-
9 trol and Prevention (referred to in this Act as the
10 “CDC”), healthcare-associated infections (referred
11 to in this Act as “HAI”) are one of the top 10 lead-
12 ing causes of death in the United States.

13 (4) In American hospitals alone, HAI account
14 for an estimated 1,700,000 infections and 99,000
15 associated deaths each year. In 70 percent of these
16 deaths, the bacteria are resistant to at least one
17 commonly used antibiotic.

18 (5) Dr. John Jernigan, Chief of Interventions
19 and Evaluations at the CDC, estimates that HAI in
20 hospitals result in up to \$27,500,000,000 in addi-
21 tional healthcare costs annually. The growing prob-
22 lem of antibiotic resistance, which affects the most
23 common and least expensive antibiotics first, also
24 shifts utilization toward more expensive antibiotics.

1 (6) Methicillin-resistant *Staphylococcus aureus*
2 (referred to in this Act as “MRSA”), one of the
3 most dangerous forms of antibiotic-resistant staph
4 infections, highlights the magnitude of the problem.
5 A recent study by the CDC estimates that nearly
6 95,000 people became infected with invasive MRSA
7 in 2005 in the United States, resulting in 19,000
8 deaths, more than the number who died from HIV/
9 AIDS, Parkinson’s disease, emphysema, or homicide.
10 A vast majority (85 percent) of these infections were
11 associated with healthcare treatment.

12 (7) MRSA also affects individuals outside the
13 healthcare setting and in the community. Recent
14 weeks have seen an increase by health and education
15 officials in reported staph infection outbreaks, in-
16 cluding antibiotic-resistant strains. These infections
17 have occurred in New York, Kentucky, Virginia,
18 Maryland, Illinois, Ohio, North Carolina, Florida,
19 and the District of Columbia.

20 (8) The problem of antibiotic-resistant infec-
21 tions is not limited to MRSA. High levels of resist-
22 ance in enterococci, *Klebsiella pneumonia*,
23 *Pseudomonas aeruginosa*, and *E. coli* have also been
24 reported.

(9) Antibiotic-resistant infections have been discovered in troops coming back from Iraq and Afghanistan. A CDC study showed that between March and October 2003, 145 United States service members at military treatment facilities were infected or colonized with a multidrug-resistant gram-negative bacterium called *Acinetobacter baumannii*. The most likely source of this outbreak was bacteria within deployed field hospitals.

(10) Despite this significant public health threat, information on community and healthcare-associated infections (referred to in this Act as “CHAI”) is incomplete and unreliable. Policymakers, healthcare providers, and individual consumers have little information about hospital infection rates, making it difficult to diagnose the scope of the problem and evaluate current infection prevention efforts, and assess potential remedies.

SEC. 3. DEFINITIONS.

In this Act:

(1) ADMINISTRATOR.—The term “Administrator” means the Administrator of the Centers for Medicare & Medicaid Services.

(2) AHRQ.—The term “AHRQ” means the Agency for Healthcare Research and Quality.

1 (3) CHAI.—The term “CHAI” means commu-
2 nity and healthcare-associated infections.

3 (4) DIRECTOR.—The term “Director” means
4 the Director of the Centers for Disease Control and
5 Prevention, unless otherwise specifically designated.

6 (5) HAI.—The term “HAI” means healthcare-
7 associated infections, which are infections that pa-
8 tients acquire during the course of receiving treat-
9 ment for other conditions within a healthcare set-
10 ting.

11 (6) HOSPITAL.—The term “hospital” means a
12 subsection (d) hospital (as defined in section
13 1886(d)(1)(B) of the Social Security Act (42 U.S.C.
14 1395ww(d)(1)(B))).

15 (7) INTERAGENCY WORKING GROUP.—The term
16 “interagency working group” means the interagency
17 working group on community and healthcare-associ-
18 ated infections established under section 9.

19 (8) MRSA.—The term “MRSA” means
20 Methicillin-resistant *Staphylococcus aureus*.

21 (9) SECRETARY.—The term “Secretary” means
22 the Secretary of Health and Human Services.

1 **SEC. 4. COMMUNITY AND HEALTHCARE-ASSOCIATED IN-**
2 **FECTION CONTROL PROGRAM.**

3 (a) ESTABLISHMENT OF BEST PRACTICES GUIDE-
4 LINES FOR INFECTION CONTROL.—

5 (1) IN GENERAL.—Not later than 90 days after
6 the date of enactment of this Act, AHRQ in collabo-
7 ration with CDC shall develop best-practices guide-
8 lines for internal infection control plans to prevent,
9 detect, control, and treat CHAI at hospitals.

10 (2) REQUIREMENTS.—In carrying out para-
11 graph (1), AHRQ shall—

12 (A) establish a set of best practices with
13 supporting justification of their appropriateness
14 and effectiveness based on nationally-recognized
15 or evidence-based standards, which practices
16 may include—

17 (i) the establishment of an infection
18 control oversight committee; and

19 (ii) the establishment of measures for
20 the prevention, detection, control, and
21 treatment of CHAI, such as—

22 (I) staff training and education
23 on CHAI prevention and control, in-
24 cluding the monitoring and strict en-
25 forcement of hand hygiene procedures;

1 (II) a system to identify, des-
2 ignate, and manage patients known to
3 be colonized or infected with CHAI,
4 including diagnostic surveillance proc-
5 esses and policies, procedures and
6 protocols for staff who may have had
7 potential exposure to a patient or resi-
8 dent known to be colonized or infected
9 with a CHAI, and an outreach process
10 for notifying a receiving healthcare fa-
11 cility of any patient known to be colo-
12 nized or infected with CHAI prior to
13 transfer of such patient within or be-
14 tween facilities;

15 (III) the development and imple-
16 mentation of an infection control
17 intervention protocol that may include
18 active detection and isolation proce-
19 dures, the alternation of the physical
20 plan of a hospital, the appropriate use
21 of anti-microbial agents, and other in-
22 fection control precautions for general
23 surveillance of infected or colonized
24 patients;

1 (B) work in collaboration with other agen-
 2 cies and organizations whose area of expertise
 3 is the identification, treatment, and prevention
 4 of infectious disease;

5 (C) publish proposed guidelines for inter-
 6 nal infection control plans;

7 (D) provide for a comment period of not
 8 less than 90 days; and

9 (E) establish final guidelines, taking into
 10 consideration any comment received under sub-
 11 paragraph (D).

12 (b) CONSULTATION OF BEST PRACTICES GUIDE-
 13 LINES.—The Administrator shall consult best practices
 14 guidelines in evaluating hospitals infection control plans
 15 as a condition of participation in the Medicare program.

16 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
 17 purpose of carrying out this section, there is authorized
 18 to be appropriated such sums as may be necessary for
 19 each of fiscal years 2008 through 2012.

20 **SEC. 5. COLLECTION, REPORTING, AND COMPILATION OF**
 21 **COMMUNITY AND HEALTHCARE-ASSOCIATED**
 22 **INFECTION DATA.**

23 (a) IN GENERAL.—Not later than 120 days after the
 24 date of enactment of this Act, hospitals shall report infor-
 25 mation about CHAI to the CDC National Healthcare

1 Safety Network (NHSN), which shall be used by the CDC
2 to develop a national database of infection rates in hos-
3 pitals. With respect to reporting such information, the fol-
4 lowing shall apply:

5 (1) Hospitals shall meet data reporting stand-
6 ards as required by the NHSN, including time-
7 frames, case-finding techniques, submission formats,
8 infection definitions and other relevant terms, meth-
9 odology for surveillance of infections, risk-adjust-
10 ment techniques, or other specifications necessary to
11 render the incoming data valid, consistent, compat-
12 ible, and manageable.

13 (2) Hospitals shall submit data that allows the
14 CDC to distinguish between—

15 (A) infections that are present in patients
16 upon their admission to the hospital;

17 (B) infections that occur during a patient's
18 hospital stay; and

19 (C) infections caused by multiple drug re-
20 sistant organisms and nondrug resistant orga-
21 nisms.

22 (3) The CDC shall have the authority to make
23 such orders, findings, rules, and regulations as nec-
24 essary to ensure that hospitals accurately and timely
25 track and report data.

1 (b) CONSULTATION.—The CDC shall review and re-
2 vise NHSN standards as appropriate, working in consulta-
3 tion with the Centers for Medicare & Medicaid Services,
4 AHRQ, and national organizations engaged in healthcare
5 quality measurement and reporting.

6 (c) DATA HARMONIZATION.—The Director shall work
7 in collaboration with the Administrator to support the har-
8 monization of data for purposes of developing a national
9 database of infections rates in hospitals and other pur-
10 poses determined to be appropriate.

11 (d) DISSEMINATION OF DATA.—Not later than 1
12 year after the date of enactment of this Act, subject to
13 the confidentiality of patient records, the CDC shall—

14 (1) make data available to interested research-
15 ers;

16 (2) make data available to interested State
17 Health Departments;

18 (3) produce useful and accessible reports for
19 the public to allow for comparisons of HAI rates
20 across hospitals; and

21 (4) use data to assist hospitals in evaluating
22 and formulating best practices strategies to reduce
23 infection rates.

24 (e) PRIVACY OF DATA.—Notwithstanding any other
25 provision of Federal, State, or local law, the infection data

1 collected pursuant to this Act shall be privileged and shall
2 not be—

3 (1) subject to admission as evidence or other
4 disclosure in any Federal, State, or local civil or ad-
5 ministrative proceeding; and

6 (2) subject to use in a State or local discipli-
7 nary proceeding against a hospital or provider.

8 (f) AUTHORIZATION OF APPROPRIATIONS.—For the
9 purpose of carrying out this section, there is authorized
10 to be appropriated such sums as may be necessary for
11 each of fiscal years 2008 through 2012.

12 **SEC. 6. QUALITY IMPROVEMENT PAYMENT PROGRAM.**

13 (a) PAY FOR PERFORMANCE INITIATIVES REPORT.—
14 Not later than 90 days after the date of enactment of this
15 Act, the Administrator shall submit to Congress a report
16 studying the feasibility of reducing HAI rates through a
17 Quality Improvement Payment Program.

18 (b) PROGRAM.—The report under subsection (a) shall
19 consider such factors as—

20 (1) patient demographics, such as—

21 (A) the median income of patients;

22 (B) percentage of minority patients; and

23 (C) disease condition;

24 (2) hospital characteristics, such as—

25 (A) median income;

1 (B) population density of the hospital zip
 2 code locale;

3 (C) university affiliation; and

4 (D) hospital size as indicated by the num-
 5 ber of beds; and

6 (3) other factors as determined to be appro-
 7 priate by the Centers for Medicare & Medicaid Serv-
 8 ices.

9 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
 10 purpose of carrying out this section, there is authorized
 11 to be appropriated such sums as may be necessary for
 12 each of fiscal years 2008 through 2012.

13 **SEC. 7. PUBLIC AWARENESS CAMPAIGN.**

14 (a) IN GENERAL.—The Director shall award grants
 15 to States for the purpose of enabling the States to carry
 16 out public awareness campaigns to provide public edu-
 17 cation and increase awareness with respect to the issue
 18 of reducing, preventing, detecting, and controlling CHAI.

19 (b) REQUIREMENTS.—To be eligible for a grant
 20 under subsection (a), a State shall provide assurances to
 21 the Secretary that the State campaign to be conducted
 22 under the grant shall—

23 (1) provide information on the prevention and
 24 control of CHAI, including appropriate antibiotic
 25 use, causes and symptoms, and management, treat-

1 ment and reduction methods, in healthcare settings
2 and non-healthcare settings;

3 (2) provide information to healthcare providers
4 and the public, including schools, non-profit organi-
5 zations, and private-sector entities; and

6 (3) work with members of the community to
7 promote awareness and education, including hos-
8 pitals, school health centers, schools, local govern-
9 ments, doctors' offices, prisons, jails, and other
10 public- and private-sector entities.

11 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
12 purpose of carrying out this section, there is authorized
13 to be appropriated such sums as may be necessary for
14 each of fiscal years 2008 through 2012.

15 **SEC. 8. EXPANSION AND COORDINATION OF ACTIVITIES OF**
16 **THE NATIONAL INSTITUTES OF HEALTH RE-**
17 **GARDING COMMUNITY AND HEALTHCARE-AS-**
18 **SOCIATED INFECTIONS.**

19 (a) COMMUNITY AND HEALTHCARE-ASSOCIATED IN-
20 FECTIONS INITIATIVE THROUGH THE NATIONAL INSTI-
21 TUTES OF HEALTH.—

22 (1) EXPANSION AND INTENSIFICATION OF AC-
23 TIVITIES.—

24 (A) IN GENERAL.—The Director of Na-
25 tional Institutes of Health (referred to in this

1 section as the “Director”), in coordination with
 2 the directors of the other national research in-
 3 stitutes (as appropriate), may expand and in-
 4 tensify programs of the National Institutes of
 5 Health with respect to research and related ac-
 6 tivities concerning CHAI.

7 (B) COORDINATION.—The directors re-
 8 ferred to in paragraph (1) may jointly coordi-
 9 nate the programs referred to in such para-
 10 graph and consult with additional Federal offi-
 11 cials, voluntary health associations, medical pro-
 12 fessional societies, and private entities, as ap-
 13 propriate.

14 (2) PLANNING GRANTS AND CONTRACTS FOR
 15 INNOVATIVE RESEARCH IN CHAI.—

16 (A) IN GENERAL.—In carrying out sub-
 17 section (a)(1) the Director may award planning
 18 grants or contracts for the establishment of new
 19 research programs, or the enhancement of ex-
 20 isting research programs, that focus on CHAI.

21 (B) RESEARCH.—In awarding planning
 22 grants or contracts under paragraph (1), the
 23 Director may give priority to—

- 24 (i) collaborative partnerships, which
 25 may include academic institutions, private

1 sector entities, or nonprofit organizations
2 with a focus on infectious disease science,
3 medicine, public health, veterinary medi-
4 cine, or other discipline impacting or influ-
5 enced by emerging infectious diseases;

6 (ii) research on the most effective cop-
7 per-based applications to stem infections in
8 military and civilian healthcare facilities;
9 and

10 (iii) research on new rapid diagnostic
11 techniques for antibiotic-resistant bacteria.

12 (b) REPORT.—Not later than 6 months after the date
13 of enactment of this Act, the Secretary, in collaboration
14 with the Director, the Commissioner of Food and Drugs,
15 and the Director of the National Institutes of Health, shall
16 prepare and submit to the appropriate committees of the
17 Congress a report that describes the obstacles to anti-in-
18 fection, especially antibacterial, drug research and develop-
19 ment. Such report shall—

20 (1) identify, in concurrence with infectious dis-
21 ease clinicians and appropriate professional associa-
22 tions, the infectious pathogens that are (or are likely
23 to become) a significant threat to public health be-
24 cause of drug resistance or other factors;

1 (2) identify those incentives that may already
2 exist through Federal programs, such as Orphan
3 Product designation, including an explanation of
4 how such programs would apply to infectious dis-
5 eases and in particular resistant bacterial infections;

6 (3) recommend strategies to publicize current
7 incentives available to encourage anti-infective, espe-
8 cially antibacterial, drug research and development;

9 (4) recommend additional regulatory and legis-
10 lative solutions to stimulate appropriate anti-infec-
11 tive, especially antibacterial, drug research and de-
12 velopment;

13 (5) update the progress made in response to the
14 “Public Health Action Plan to Combat Antimicrobial
15 Resistance” to include a narrative summary of ac-
16 tivities in addition to tables provided in existing
17 progress reports, highlighting where gaps remain as
18 well as obstacles to future progress; and

19 (6) recommend strategies to strengthen the
20 Federal response to antimicrobial resistance, as out-
21 lined in the Action Plan, in particular additional ac-
22 tions needed to address remaining gaps or obstacles
23 to progress in implementing the Plan, as well as
24 Federal funding needs.

1 (c) PUBLIC INFORMATION.—The coordinating com-
 2 mittee shall make readily available to the public informa-
 3 tion concerning the research, education, and other activi-
 4 ties relating to CHAI, that are conducted or supported
 5 by the National Institutes of Health.

6 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
 7 authorized to be appropriated such sums as may be nec-
 8 essary for each of fiscal years 2008 through 2012 to carry
 9 out this section.

10 **SEC. 9. INTERAGENCY WORKING GROUP ON COMMUNITY**
 11 **AND HEALTHCARE-ASSOCIATED INFECTIONS.**

12 (a) ESTABLISHMENT.—The Secretary, in coordina-
 13 tion with the Administrator, shall establish an interagency
 14 working group on CHAI to consider issues relating to the
 15 reduction and prevention of these infections.

16 (b) MEMBERSHIP.—The interagency working group
 17 shall be composed of a representative from each Federal
 18 agency (appointed by the head of each such agency) that
 19 has jurisdiction over, or is affected by, CHAI including—

20 (1) the Centers for Medicare & Medicaid Serv-
 21 ices;

22 (2) the Centers for Disease Control and Preven-
 23 tion;

24 (3) the Health Resources and Services Adminis-
 25 tration;

- 1 (4) the Agency for Healthcare Research and
2 Quality;
3 (5) the Food and Drug Administration;
4 (6) the National Institutes of Health;
5 (7) the Department of Agriculture;
6 (8) the Department of Defense;
7 (9) the Department of Veterans Affairs;
8 (10) the Environmental Protection Agency; and
9 (11) such other Federal agencies as determined
10 appropriate.

11 (c) DUTIES.—The interagency working group shall—

12 (1) work in collaboration with the Interagency
13 Task Force on Anti-microbial Resistance;

14 (2) facilitate communication and partnership on
15 infection prevention and quality health-related
16 projects and policies;

17 (3) serve as a centralized mechanism to coordi-
18 nate a national effort—

19 (A) to discuss and evaluate evidence and
20 knowledge on infection prevention;

21 (B) to determine the range of effective,
22 feasible, and comprehensive actions to improve
23 healthcare quality related to CHAI; and

1 (C) to examine and better address the
2 growing impact of CHAI in communities
3 throughout the United States;

4 (4) coordinate plans to communicate research
5 results relating to CHAI prevention and control to
6 enable reporting and outreach activities to produce
7 more useful and timely information;

8 (5) consider and determine the feasibility of es-
9 tablishing an active surveillance program involving
10 other entities (such as athletic teams or correctional
11 facilities) for the purpose of identifying those indi-
12 viduals in the community that are colonized and at
13 risk of susceptibility to and transmission of bacteria;

14 (6) develop an appropriate research agenda for
15 Federal agencies;

16 (7) develop recommendations regarding evi-
17 dence-based best practices, model programs, effective
18 guidelines, and other strategies for promoting CHAI
19 prevention and control;

20 (8) monitor Federal progress in meeting spe-
21 cific CHAI prevention and control promotion goals;
22 and

23 (9) not later than 2 years after the date of en-
24 actment of this Act, submit to Congress a report
25 that describes the appropriateness and effectiveness

1 of best practices guidelines developed by the Centers
 2 for Disease Control and Prevention for infection
 3 control plans.

4 (d) MEETINGS.—

5 (1) IN GENERAL.—The interagency working
 6 group shall meet at least 6 times each year.

7 (2) ANNUAL CONFERENCE.—The Secretary
 8 shall sponsor an annual conference on CHAI preven-
 9 tion, detection, and control to enhance coordination
 10 and share best practices in CHAI data collection,
 11 analysis, and reporting.

12 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
 13 authorized to be appropriated such sums as may be nec-
 14 essary to carry out this section.

15 **SEC. 10. GOVERNMENT ACCOUNTABILITY OFFICE REPORT**
 16 **ON COMMUNITY AND HEALTHCARE-ASSOCI-**
 17 **ATED INFECTIONS.**

18 Not later than 2 years after the date of enactment
 19 of the Act, the Government Accountability Office shall
 20 submit to Congress a report on the impact of this Act
 21 on—

22 (1) the prevalence of CHAI; and

23 (2) the quality and availability of data about
 24 CHAI.

1 **SEC. 11. PREEMPTION.**

2 Nothing in this Act shall be construed to preempt ex-
3 isting State laws, except to the extent that such State laws
4 would result in the establishment of duplicative or con-
5 flicting surveillance or reporting requirements.

○